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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,530

09/01/2006

Kaoru Miyamoto

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2171

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EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,530	Applicant(s) MIYAMOTO ET AL.	
	Examiner Michael C. Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-17-08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim 7 has been canceled. Claims 1-6 and 8-10 are pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-6, 8 and 9, in the reply filed on 12-16-08 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for differentiating mesenchymal stem cells by transfecting the cells with a vector encoding steroidogenic factor 1 (sf-1) then stimulating the cells with cAMP such that the cells differentiate into cells that produce progesterone and androgen, does not reasonably provide enablement for differentiating mesenchymal stem cells into any hormone-producing cells, using the sf-1 protein to induce differentiation in culture, inducing differentiation in the absence of cAMP or transplanting the cells in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 1 is drawn to differentiating mesenchymal stem cells into steroid hormone-producing cells by stimulating the cells by "a transcription factor (SF-1)." The claim encompasses differentiating mesenchymal stem cells into any hormone-producing cells,

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using the sf-1 protein or DNA encoding sf-1 to induce differentiation in culture, and inducing differentiation in the absence of cAMP.

Val (Nuclear Receptor, 2003, Vol. 1, No. 8, pg 1-23) taught SF-1 acts on numerous genes, some of which are involved in hormone production (pg 7, "Genes implicated in steroidogenesis"). The effects of SF-1 on target genes remain unclear (pg 9, col. 2 "SF-1 target genes: unanswered questions").

Crawford (Mol. Cell. Biol., July 1997, Vol. 17, No. 7, pg 3997-4006) taught differentiating embryonic stem (ES) cells by transfecting the cells with a vector encoding steroidogenic factor 1 (sf-1) then stimulating the cells with cAMP such that the cells differentiate into cells that produce progesterone (pg 3998, col. 1, ES cell culture; pg 4000, col. 1, "ES cells differentiate...").

The specification teaches differentiating mouse mesenchymal stem cells by transfecting the cells with a vector encoding rat steroidogenic factor 1 (sf-1) then stimulating the cells with cAMP such that the cells differentiate into cells that produce progesterone and androgen (pg 7, Example 2). The specification also teaches differentiating human mesenchymal stem cells by transfecting the cells with a vector encoding steroidogenic factor 1 (sf-1) then stimulating the cells with cAMP (pg 8, Example 3); the specification does not teach the human cells differentiate into cells that produce hormones.

The specification and the art at the time of filing do not teach how to differentiate mesenchymal stem cells into any hormone-producing cells, how to use the sf-1 protein to induce differentiation in culture, or how to induce differentiation in the absence of

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cAMP. Given the unpredictability of the effects of SF-1 on target genes taken with the teachings in the specification it would have required those of skill undue experimentation to determine how to use SF-1 to make any hormone-producing cells from mesenchymal cells, how to use SF-1 protein in culture or how to induce differentiation into progesterone cells in the absence of cAMP.

Claim 6 requires transplanting the hormone-producing cells to mammalian reproductive organs. The specification suggests transplanting the cells produced into a mammalian reproductive organ. The specification does not teach what type of cells are produced after differentiation, the amount of steroid produced by the cells or how to target the hormone produced to tissues of interest within the reproductive organ. The art does not teach how to use non-descript cells that produce an undisclosed amount of hormone for transplantation into mammalian reproductive organs. Without such guidance, it would have required those of skill undue experimentation to determine how to use hormone-producing cells to mammalian reproductive organs.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "transcription factor (SF-1)" does not make sense. SF-1 stands for steroidogenic factor 1. The phrase" should be steroidogenic factor (SF-1)."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Gondo (Genes to Cells, 2004, Vol. 9, pg 1239-1247)

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Patent Examiner